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Remarks

The above-identified application has been carefully reviewed in light of the Examiner's office action mailed on December 3, 2007. Since the above-identified application has been give special status, this response to the office action is due February 4, 2008.

Applicant has again reviewed the specification as requested by the Examiner. No further corrections have become apparent.

Claims 33, 35, 36, 38, 41, 44, 45, 55, 57-59, 61-65, 67-70 have been rejected under 35 U.S.C. 112, first paragraph. Applicant traverses this rejection.

The Examiner, while acknowledging that the specification is enabling for treating hot flashes, contends that the specification does not provide enablement for preventing hot flashes.

Each of the present claims is directed to "a method of treating hot flashes associated with menopause in a woman". Therefore, as acknowledged by the Examiner, all of the present claims are enabled.

None of the present claims is directed to preventing hot flashes. Dependent claims 67-70 recite that "the placing step ... is effective to prevent a hot flash associated with menopause from spreading throughout the body of the woman". Such spreading of a hot flash throughout the body of the woman represents an increase in the severity of the hot flash. Thus, by preventing such spreading of a hot flash through the body of the woman, the present placing step, as recited in the present claims 67-70, reduces and/or controls and/or manages the severity of the hot flash, and does not prevent the hot flash

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from occurring. Such reducing/controlling/managing the severity of the hot flash is fully consistent with treating a hot flash, as recited in the present specification. See, for example, page 7, lines 27-29 and page 17, lines 14-27 of the present specification.

In view of the above, applicant submits, and the Examiner acknowledges, that the present claims 33, 35, 36, 38, 41, 44, 45, 55, 57-59, 61-65 and 67-70 directed to treating hot flashes associated with menopause in a woman are enabled and satisfy the requirements of 35 U.S.C. 112, first paragraph. Therefore, applicant respectfully requests that the rejection of the present claims under this statutory provision be withdrawn.

Claims 33, 35, 41, 44, 45, 61, 63, 69 and 70 have been rejected under 35 U.S.C. 102(b) as being anticipated by the "BeKOOL" product by Kobayashi Healthcare, Inc., and was presented as: "Product Concept Test" (PCT). Claims 36, 38, 55, 57-59, 62, 64, 65, 67 and 68 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the "BeKOOL" product in view of any of JP 2002119529 (JP '529) or U.S. Patent 6,224,899 (U.S. '899). Applicant vigorously traverses each of these rejections.

On January 31, 2008, applicant's attorney telephoned Examiner Galli seeking to more clearly understand the basis of the above-noted rejections. Examiner Galli stated that the "BeKOOL" product (and the pamphlet) she was referring to in the rejections was the material identified as "BeKOOL" HOT FLASH, Kobayashi Healthcare, Inc., listed in the PTO-892 form provided with the present Office Action. Applicant's attorney told Examiner Galli that the "BeKOOL" HOT FLASH material listed in the PTO 892 was undated, and was not prior art against the

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present claims. Examiner Galli agreed to have the Office Action and this RESPONSE C reviewed by others at the Patent and Trademark Office to determine whether the citation of this undated, non-prior material as an anticipatory reference is appropriate. Applicant respectfully requests that such review be conducted.

The present invention is directed to methods of treating hot flashes associated with menopause in a woman.

Independent claim 33 defines embodiments of the invention which comprise providing a woman experiencing a hot flash associated with menopause or prone to experiencing hot flashes associated with menopause with at least one cooling device in a package having instructions to remove the at least one cooling device from the package and to place the at least one cooling device at a location on the upper back of the woman to thereby treat the hot flash associated with menopause.

Independent claim 55 defines embodiments of the invention which comprise removing a cooling device from a package having instructions for treating hot flashes associated with menopause using the cooling device on an upper back of a woman, and thereafter placing the cooling device at a location on an upper back of a woman who is experiencing a hot flash associated with menopause or is prone to experiencing hot flashes associated with menopause, the cooling device comprising a water-containing gel.

Independent claim 61 defines embodiments of the invention which comprise removing a cooling device from a package having instructions to place the cooling device at a location on an upper back of a woman experiencing a hot flash associated with

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menopause or prone to experiencing hot flashes associated with menopause, and placing the cooling device at a location on an upper back of a woman who is experiencing a hot flash associated with menopause or is prone to experiencing hot flashes associated with menopause.

A hot flash associated with menopause, such as caused by hormonal changes associated with menopause in a woman, is often experienced as a wave-like warming sensation throughout a woman's body, for example, radiating from the front of the chest. This wave-like warming sensation can be highly unpleasant, even embarrassing due to a flushing of the face. Applicant, and applicant alone, has discovered that, by placing a cooling device specifically at a location on an upper back of a woman experiencing a hot flash or prone to experiencing hot flashes, the hot flash can be successfully treated, for example, the wave-like warming sensation and the flushing of the face are significantly lessened in intensity.

Applicant has surprisingly and unexpectedly found that placing a cooling device at a location on the upper back, for example, at a region in proximity to the cervical and thoracic vertebrae, such as between the C3 vertebrae and the T6 vertebrae, of a woman experiencing a hot flash or prone to experiencing hot flashes, for example, during the hot flash or in anticipation of a hot flash, that the hot flash is effectively and advantageously treated, such as by being prevented from spreading throughout the woman's body. This is a surprising and unexpected advantage of practicing applicant's invention, as recited in the present claims.

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Further, and importantly the claimed methods allow a woman to easily and discreetly treat menopausal hot flashes at virtually any time, no matter where the woman is or what she is doing. For example, application of the cooling device at a location on an upper back is very effective in reducing the hot flash symptoms, and, in addition, because the upper back is a discreet location of the body, advantageously facilitates privacy in that the cooling device located on the upper back can be discreetly concealed under clothing. Thus, the present methods very effectively treat menopausal hot flashes, and do so discretely, without embarrassing the woman. This surprising and unexpected combination of advantages, that is effective and successful treatment of menopausal hot flashes in a discreet manner, while respecting the woman's privacy and allowing the woman to carry on with her normal activities, achieved in accordance with the present invention, gives the woman more comfort and more confidence during an especially difficult time in her life.

In support of the rejection under 35 U.S.C. 102(b), the Examiner states that "BeKOOL" HOT FLASH is a cooling gel sheet used for treating hot flashes, and that the Product Concept Test (PCT) implies that the gel sheets have been in use for hot flashes before August 14, 2003, the date of the PCT.

The undated "BeKOOL" HOT FLASH material relied on by the Examiner is not prior art against the present claims, which claim the benefit of U.S. Provisional Application 60/563,237 filed April 16, 2004. The Examiner has provided no basis, and applicant believes no basis exists, for the present rejections based on the cited "BeKOOL" HOT FLASH material being prior art.

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The "BeKOOL" HOT FLASH material cited by the Examiner were not available until well after April 16, 2004.

The present claims are fully supported by U.S. Provisional Application 60/563,237, filed April 16, 2004, a copy of which is attached hereto.

Both of the present rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) are based on the non-prior art cited "BeKOOL" HOT FLASH material as either the sole basis for the rejection or the primary basis for the rejection. Applicant submits that these rejections are not based on prior art (because the cited "BeKOOL" HOT FLASH material is not prior art against the present claims) and, therefore, cannot properly be maintained.

In view of the above, applicant respectfully requests that the rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) be withdrawn and that the present claims be allowed.

Moreover, the Product Concept Test (PCT) does not disclose, teach, imply or suggest the present invention. For example, the PCT does not disclose, teach, imply or even suggest a method of treating hot flashes associated with menopause in a woman comprising providing a woman experiencing a hot flash associated with menopause or prone to experiencing hot flashes associated with menopause with at least one cooling device in a package having instructions to remove the at least one cooling device from the package and to place the at least one cooling device at a location on the upper back of the woman to thereby treat the hot flash associated with menopause, as recited in claim 33.

Further, the PCT does not disclose, teach, imply or even suggest a method of treating hot flashes associated with menopause in a woman in which the method comprises removing a

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cooling device, comprising a water-containing gel, from a package having instructions for treating hot flashes associated with menopause using the cooling device on an upper back of a woman; and, thereafter placing the cooling device at a location on an upper back of a woman who is experiencing a hot flash or is prone to experiencing hot flashes, as recited in claim 55.

In addition, the PCT does not disclose, teach, imply or even suggest a method of treating hot flashes associated with menopause in a woman in which the method comprises the steps of removing a cooling device from a package having instructions to place the cooling device at a location on an upper back of a woman experiencing a hot flash associated with menopause or prone to experiencing hot flashes associated with menopause, and placing the cooling device removed from the package at a location on an upper back of a woman who is experiencing a hot flash or is prone to experiencing hot flashes, as recited in claim 61.

The PCT does not disclose, teach, imply or even suggest instructing a user to place the cooling device on any specific site, let alone at a location on the upper back of the woman, as recited in the present claims. While the Examiner states that the PCT implies that a product was used to treat hot flashes before August 14, 2003, a careful reading of the PCT shows that the PCT does not so imply. In particular, the PCT is based on consumer opinion interviews, and not on actual use of any product for any specific purpose. The PCT does not include any mention of any location on the body of a woman, let alone the upper back. As noted above, the PCT does not disclose, teach or even suggest instructing a user to place, or placing, a cooling

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device on any site, let alone at a location on the upper back of the woman, as recited in the present claims.

Moreover, the PCT does not recognize or even suggest the surprising, unexpected combination of advantages, that is effective and successful treatment of menopausal hot flashes in a discreet manner, while respecting the woman's privacy and allowing the woman to conduct her normal activities, achieved in accordance with the present invention. The present claims and the surprising and unexpected advantages achieved by applicant are unpredictable from the deficient teachings of the PCT.

In summary, the PCT is grossly deficient with respect to the present claims. Only after knowing of applicant's disclosure and invention would one of ordinary skill in the art even consider the present methods, let alone do so and expect to obtain the surprising, unexpected and unpredictable combination of advantages achieved only by applicant. Thus, applicant submits that the rejections based in whole or in part on the PCT are not properly based since they are derived from an improper hindsight view of applicant's own disclosure and invention.

In view of the above, applicant submits that the PCT provides no motivation, no other reasonable or rational basis and no common sense basis for making obvious the present invention, and obtaining the surprising, unexpected and unpredictable combination of advantages achieved only by applicant.

Therefore, applicant submits that the present claims, that is claims 33, 35, 36, 38, 41, 44, 45, 55, 57-59, 61-65 and 67-70, are not anticipated by and are unobvious from and patentable over the PCT under 35 U.S.C. 102(b) and 35 U.S.C. 103(a).

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The other documents cited by the Examiner do not supply the deficiencies apparent in the PCT.

JP '529 does not disclose, teach or suggest the present invention. For example, JP '529 does not disclose, teach or even suggest any methods for treating hot flashes associated with menopause in a woman, let alone methods for treating hot flashes associated with menopause in a woman experiencing such a hot flash or prone to experiencing hot flashes associated with menopause including providing a woman experiencing a hot flash or prone to experiencing hot flashes with a cooling device in a package having instructions to place a cooling device at a location on her upper back to thereby treat the hot flash (claim 33) or placing a cooling device at a location on the upper back of the woman (claims 55 and 61), as recited in the present claims.

U.S. '899 does not disclose, teach or suggest the present invention. For example, U.S. '899, like JP '529, does not disclose, teach or even suggest any methods for treating hot flashes associated with menopause in a woman, let alone methods of treating hot flashes associated with menopause in a woman experiencing such a hot flash or prone to experiencing hot flashes associated with menopause comprising providing a woman experiencing a hot flash or prone to experiencing hot flashes with a cooling device in a package having instructions to place the cooling device at a location on her upper back or placing a cooling device at a location on the upper back of the woman, as recited in the present claims.

Neither JP '529 nor U.S. '899 recognizes or even suggests the surprising, unexpected and unpredictable combination of

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advantages, that is effective and successful treatment of menopausal hot flashes in a discreet manner, while respecting the woman's privacy and allowing the woman to conduct her normal activities, achieved in accordance with the present invention. Both JP '529 and U.S. '899 are deficient with regard to the present claims.

The present specification, at page 2, acknowledges the existence of an adhesive cooling composition shaped into a sheet, and coolers carried in a woman's purse so that when a hot flash occurs, the cooler is removed from her purse and slid onto the woman's wrist.

The prior art coolers acknowledged by applicant do not disclose, teach or even suggest placing the coolers on the upper back of a woman experiencing or prone to experiencing a hot flash associated with menopause to treat the menopausal hot flash, let alone obtaining the surprising, unexpected and unpredictable combination of advantages, noted above, as achieved by applicant in accordance with the present invention.

To reiterate what has been presented in previous responses to office actions, the above-identified application has been made special because of infringement activities. Thus, it is not surprising that the non-prior art "BeKOOL" HOT FLASH material exists and are directed to claimed embodiments of the present invention.

In any event, applicant submits that the "BeKOOL" HOT FLASH material is not prior art against the present claims, and cannot properly be used to render the present claims unpatentable.

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Moreover, none of the actual prior art, taken singly or in combination, disclose, teach or even suggest the present claims and the surprising, unexpected and unpredictable combination of advantages, that is effective and successful treatment of menopausal hot flashes in a discreet manner while respecting the woman's privacy and allowing the woman to conduct her normal activities, achieved by applicant, and only applicant, in accordance with the present claims.

There simply is no motivation, no other reasonable or rational basis and no common sense basis for one of ordinary skill in the art to combine and extend the deficient teachings of the prior art to make obvious the presently claimed methods and obtain the surprising, unexpected and unpredictable combination of advantages of such methods achieved by, and only by, applicant.

Only after knowing of applicant's disclosure and invention would one of ordinary skill in the art practice the present methods, including instructing a woman experiencing a menopausal hot flash or prone to experiencing menopausal hot flashes to place, or placing, a cooling device on the upper back of the woman and expect to obtain, let alone obtain the unexpected, surprising and unpredictable combination of advantages achieved by applicant and applicant alone.

In view of the above, applicant submits that the present claims, that is claims 33, 35, 36, 38, 41, 44, 45, 55, 57-59, 61-65 and 67-70, are not anticipated by and are unobvious from and patentable over the prior art, in particular, the PCT, JP '529 and/or U.S. '899 under 35 U.S.C. 102(b) and 103(a).

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Applicant submits that each of the present dependent claims is separately patentable over the prior art. For example, the prior art does not disclose, teach or suggest the present apparatus and systems including the addition feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

In conclusion, applicant has shown that the present claims, that is, claims 33, 35, 36, 38, 41, 44, 45, 55, 57-59, 61-65, and 67-70 are not anticipated by and are unobvious from and patentable over the prior art under 35 U.S.C. 102(b) and 103 (a). Therefore, applicant respectfully requests the Examiner to pass the above-identified application to issuance at an early date. Should any matters remain unresolved, the Examiner is requested to call applicant's attorney at the telephone number given below.

Respectfully submitted,



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